

### **REMARKS/ARGUMENTS**

The above-identified application has been reviewed in light of the Final Office Action mailed on May 14, 2009. Claims 1-40 are currently pending. Applicants respectfully submit that Claims 1-40 are allowable over the references of record. In view of the following remarks and arguments, Applicants respectfully request favorable reconsideration and allowance of the above-identified application.

Claims 1-40 stand rejected on the ground of nonstatutory obviousness-type patenting as being unpatentable over claims 1-37 of U.S. Patent No. 7,226,434. As noted by Applicants in the prior Amendment, Applicants maintain that they will file a suitable terminal disclaimer upon indication that the claims are otherwise allowable.

In the Office Action, Claims 1-37 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,287,278 to Woehr et al. ("Woehr"). Applicants respectfully submit, however, that Woehr fails to disclose each and every element recited in Claims 1-37 as presented herein.

Under 35 U.S.C. § 102(b), to anticipate a claim, a reference must disclose each and every element set forth in the claim. *See* MPEP § 2131.

Independent Claim 1 recites, inter-alia, a safety shield comprising: a piercing member...a clip defining a first cavity... the clip being movable from a first orientation to a second orientation to reposition the first cavity from a movable orientation to a binding orientation... the clip including a first leg ...the clip further including a second leg having a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation... wherein the first leg and the second leg are biased for convergent movement...

Independent Claim 15 recites, inter-alia, a safety shield comprising: a piercing member...a clip including a plate...the clip being rotatable from a first orientation to a second orientation to reposition the cavity relative to the longitudinal axis of the piercing member from a sliding orientation to a binding orientation... the clip including a first leg ...the clip including a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation... wherein the legs are resiliently biased for convergent movement...

Independent Claim 20 recites, inter-alia, a safety needle shield apparatus comprising: a needle...a clip including a plate oriented in an axis transverse to the longitudinal axis of the needle and defining a slot dimensioned for movement of the needle therethrough, the clip being rotatable from a first orientation to a second orientation to reposition the cavity relative to the longitudinal axis of the needle from a sliding orientation to a binding orientation... the clip including a first leg...the clip further including a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the needle in both the first orientation and the second orientation of the clip... wherein the legs are resiliently biased for convergent movement...

Independent Claim 26 recites, inter-alia, a safety needle shield comprising: a needle... a clip defining a first cavity...the clip being movable from a first orientation to a second orientation...the clip including a first leg that defines a second cavity dimensioned for movement of the needle therethrough, wherein the first leg has a distal part being configured to engage a medical device when the clip is in the first orientation, the clip further including a second leg having a bearing surface that engages the needle when the clip is in both the first orientation and

the second orientation... wherein the first leg and the second leg are biased for convergent movement...

Independent Claim 27 recites, inter-alia, a medical clip for use with a piercing member...the clip comprising: a first cavity dimensioned for movement of the piercing member... the clip being rotatable from a first orientation to a second orientation to reposition the first cavity relative to the longitudinal axis of the piercing member from a movable orientation to a binding orientation...a first leg...a second leg having a bearing surface configured to engage the piercing member in both the first orientation and the second orientation of the clip... wherein the first leg and the second leg are, relative to the first and second legs, biased for convergent movement...

As shown in FIGS. 3, 5 and 7, reproduced below, the presently disclosed safety shield includes a needle cannula 22 and a clip 28. As described in the presently disclosed specification:

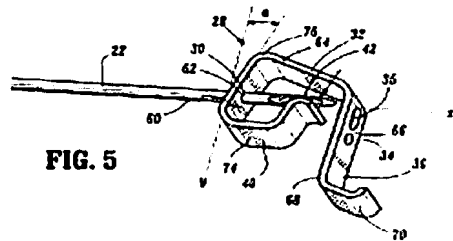
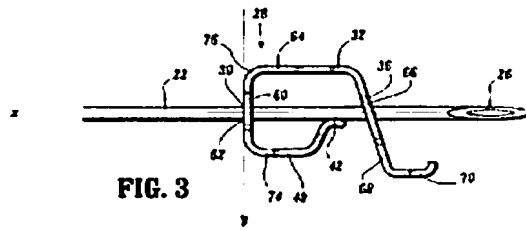
Clip 28 includes a first leg 32 that defines a second cavity, such as, for example, aperture 34 dimensioned for movement of needle cannula 22 therethrough. First leg 32 has a distal part 36 that is configured to engage a medical device, such as, for example, a catheter 38. Clip 28 includes a second leg 40 having a bearing surface 42 that engages needle cannula 22. First leg 32 and second leg 40 are resiliently biased for convergent movement.

Specification at ¶ [0055].

. . .

Legs 32, 40 convergently bias such that bearing surface 42 engages needle cannula 22 causing clip 28 to rotate aperture plate 60 an inclination  $\alpha$  (FIG. 3), relative to longitudinal axis y, as described. Correspondingly, aperture 30 rotates into the binding orientation with needle cannula 22 such that surface 62 binds against the outer surface of needle cannula 22. . . Bearing surface 42 also engages needle cannula 22 in the binding orientation to prevent movement of needle cannula 22 in the proximal and distal directions.

*Id.* at ¶¶ [0078] and [0079].



In contrast, as illustrated in FIGS 4A and 4B, reproduced below, Woehr relates to a spring clip needle guard 40a that includes a resilient portion comprising a distal arm 65 terminating at its upper end in a curved lip 66, and at its lower end in a U-shaped portion 67 which, in the ready position illustrated in FIG. 4A, contacts a bump 68 formed in the lower inner wall of the catheter hub. *See* Woehr at column 6, lines 17-24. As shown in FIG. 4A, when the catheter is in the ready position, the needle shaft passes through openings 70, 76 and 84 and rests on curved lip 66, urging arm 65 against bump 68 in the lower wall of the catheter hub. *Id.* at column 6, lines 40-43. When the needle hub and needle are retracted to the right, as viewed in FIG. 4A, by a sufficient amount, the needle tip passes below lip 66 and then releases its downward force on arm 65. *Id.* at column 6, lines 48-51. As described above, with reference to the first-described embodiment, this release of engagement of the needle shaft and spring clip arm 65 causes arm 65 to snap upwards to the retracted position illustrated in FIG. 4B. *Id.* at column 6, lines 51-54.

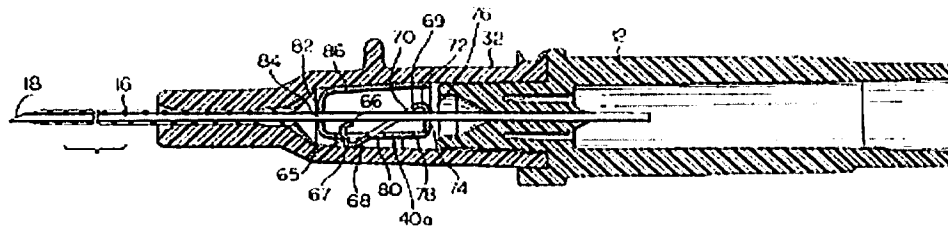


FIG. 4A

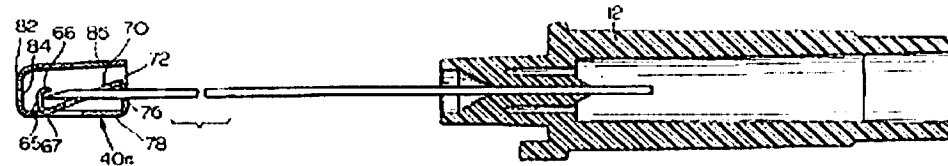


FIG. 4B

Accordingly, Woehr does not disclose, *inter alia*, a second leg having a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation... wherein the first leg and the second leg are biased for convergent movement, as recited in Claim 1.

Nor does, Woehr disclose, *inter alia*, a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the piercing member when the clip is in both the first orientation and the second orientation... wherein the legs are resiliently biased for convergent movement, as recited in Claim 15.

Furthermore, nowhere does Woehr disclose, *inter alia*, a second leg that extends from the plate and has a proximal part and a distal part, the distal part of the second leg including a bearing surface that engages the needle in both the first orientation and the second orientation of the clip... wherein the legs are resiliently biased for convergent movement, as recited in Claim 20.

With regard to Claim 26, Woehr does not disclose, *inter alia*, a second leg having a bearing surface that engages the needle when the clip is in both the first orientation and the second orientation.... wherein the first leg and the second leg are biased for convergent movement, as recited therein.

Further still, nowhere does Woehr disclose, *inter alia*, a second leg having a bearing surface configured to engage the piercing member in both the first orientation and the second orientation of the clip.... wherein the first leg and the second leg are, relative to the first and second legs, biased for convergent movement, as recited in Claim 27.

In fact, Woehr's device teaches away from Applicant's claims as recited because Woehr's arm 65 "snap[s] upwards to the retracted position illustrated in FIG. 4B," which is a divergent motion. Even, *arguendo*, if not characterizable as divergent, this motion is at best, neither divergent nor convergent as arm 65 merely "retract[s] to the position in FIG. 4B." As such, any proper interpretation of FIGS. 4A and 4B of Woehr could not be characterized as being "convergent" motion.

For at least these reasons, Applicants submit that independent Claims 1, 15, 20, 26 and 27 are patentable over Woehr and are in condition for allowance. Furthermore, since Claims 2-14, 16-19, 21-25, 28-37 depend, either directly or indirectly from 1, 15, 20, 26 and 27, it is respectfully submitted that Claims 2-14, 16-19, 21-25, 28-37 are at least patentable for the reasons that independent Claims 1, 15, 20, 26 and 27 are patentable. Accordingly, withdrawal of this rejection is respectfully requested.

In the Office Action, Claims 38-40 were rejected under 35 U.S.C. § 103(a), as being unpatentable over Woehr. Claims 38-39 depend directly or indirectly from Claim 1 and add

further features. The deficiencies of Woehr with respect to Claim 1 are noted above. Accordingly, for at least the reasons discussed above with respect to Claim 1, Applicants submit that Claims 38-39 are in condition for allowance.

Independent Claim 40 recites, *inter-alia*, a safety shield comprising: a piercing member...a clip defining a first cavity dimensioned for movement of the piercing member therethrough and being oriented in an axis transverse to the longitudinal axis of the piercing member, the clip being movable from a first orientation to a second orientation to reposition the first cavity from a movable orientation to a binding orientation...the clip including a first leg ... the clip further including a second leg having...a bearing surface that engages the piercing member in both the first orientation and the second orientation of the clip... wherein the first leg and the second leg are biased for convergent movement...

As discussed above with respect to Claims 1-37, Woehr's device teaches away from Applicant's claims as recited because Woehr's arm 65 "snap[s] upwards to the retracted position illustrated in FIG. 4B," which is a divergent motion. Even, *arguendo*, if not characterizable as divergent, this motion is at best, neither divergent nor convergent as arm 65 merely "retract[s] to the position in FIG. 4B." As such, any proper interpretation of FIGS. 4A and 4B of Woehr could not be characterized as being "convergent" motion.

As discussed above with respect to independent Claims 1, 15, 20, 26 and 27, Woehr does not disclose, *inter alia*, a bearing surface that engages the piercing member in both the first orientation and the second orientation of the clip... wherein the first leg and the second leg are biased for convergent movement... as recited in independent Claim 40. As such, for at least this reason, independent Claim 40 is in condition for allowance. Accordingly Applicants respectfully


submit that Claims 38-40 are in condition for allowance. Thus, withdrawal of this rejection is respectfully requested.

In view of the foregoing, it is respectfully submitted that all of the claims pending in the application are in condition for allowance. With this in mind, reconsideration and allowance of this application is respectfully requested.

Applicants believe that all issues raised in the Detailed Action have been responded to fully. Should the Examiner believe that a telephone interview may facilitate resolution of any outstanding issues, the Examiner is respectfully requested to telephone Applicants' undersigned attorney at the number indicated below.

An early and favorable response on the merits is earnestly solicited.

Respectfully submitted,

  
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